



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,919	01/10/2004	Syde A. Taheri	VNUS.017A	8233

20995 7590 08/26/2008
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

MASHACK, MARK F

ART UNIT	PAPER NUMBER
----------	--------------

3773

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

08/26/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/754,919	Applicant(s) TAHERI, SYDE A.	
	Examiner MARK MASHACK	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,20,21,23-30,32-38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 3, 8-19, 22, 31, 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,20,21,23-30,32-38 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/14/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 1-2, 4-7, 20-21, 23-30, 32-38, 40** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose the closure device "bidirectionally blocking blood flow". Blocking the "undesirable back flow of blood from above the blockage site" is discussed in the abstract and other areas of the specification but it is never disclosed that it is bidirectionally blocked.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 4 and 23** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what "bio-absorbable material is provided by a material" means.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 1-2, 4-5, 20-21, 23-24, 27-30, 33-38** rejected under 35 U.S.C. 102(b) as anticipated by **Callister et al. (US 6,096,052)** or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Callister et al.** in view of **Hyodoh et al. (US 2003/0040771)**.

Callister et al. disclose a stent body **11**, **16** with a bio-absorbable means **15** (Column 2, Lines 1-9; animal tissue is considered bioabsorbable) for bidirectionally blocking blood flow past said stent when it is in a closed position (Column 2, Lines 43-49; and endothelium, myocardium, and/or scar tissue would prevent blood flow through and produce clotting and fibrosis) and permitting blood flow through said stent when in an open configuration (Column 1, Lines 26-29; permeable is considered open since it allows the blood to flow through in order for the tissue to grow). The cross-section of the stent body **11** is the same when said means is in the open configuration and in the closed configuration. The time required to reach the closed configuration is adjustable by the pore size and impregnating it with growth factors and such (Column 5, Lines 25-37). The stent body **11** comprises a bioabsorbable material **16** (Column 2, Lines 1-9; animal tissue is considered bioabsorbable) in order for tissue ingrowth and favorable biocompatibility.

If that is not persuasive, **Hyohoh et al.** teaches of a similar occlusive device comprising a tubular stent body and a fibrous occluding agent (Paragraph 228-229). Said tubular stent body is composed of a bioabsorbable material in order to function as drug or nutrient delivery systems (Paragraph 209). Additionally, **Hyohoh et al.** teach of the bioabsorbable material comprising poly-L-lactic acid (Paragraph 213). It would have been obvious to one having ordinary skill in the art at the time of the invention was made to be bioabsorbable, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended

use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Doing so would allow for the release of growth factors or drugs in order to promote further tissue ingrowth (Paragraph 209-210).

9. **Claims 6-7, 25-26, 32, 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Callister et al.** in view of **Hyodoh et al.** as applied to **claims 1, 20, 29, 37** above, and further in view of **Soetikno et al.**

Callister et al. in view of **Hyodoh et al.** disclose all of the claimed limitations as stated above except for the drawstring closure device. **Soetikno et al.** teaches of a drawstring closure device that may be attached to any type of stent and closes or collapses one side of the stent that may surround the bioabsorbable means when said bioabsorbable means is in the proximal or distal end of the stent. All of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Providing the stent body with the drawstring closure device would allow the, closure, repositioning, and/or recapture of the device.

10. **Claims 1-2, 4, 6-7, 20-21, 23, 25-29, 32-37, 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over **DiMatteo et al. (US 6,440,164)** in view of **Soetokno et al. (US 2002/0143387)**.

DiMatteo et al. discloses a device including a bioabsorbable stent body with walls comprising bioabsorbable and impervious layers (Column 4, Lines 23-60).

DiMatteo et al. does not disclose the drawstring closure. **Soetikno et al.** discloses another elongated tubular stent and a drawstring located at one end. This drawstring can be incorporated into any stent. It would have been obvious to have added a drawstring to the stent of **DiMatteo et al.** in order to allow it to be easily re-positioned. When combined, the drawstring could be used to pull the end of the stent tight enough to prevent or substantially stop the flow of blood through the stent, while implanted in a vessel, since the modified stent includes an impervious layer over the stent frame, which makes one end of the wall the bioabsorbable means for bidirectionally blocking blood flow. The stent body comprises individual struts and/or wall portions having cross-sectional sizes that remain unchanged when the stent body is in its closed and open configurations due to the rigidity of the individual struts and/or wall portions.

11. **Claims 5, 24, 30, 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over **DiMatteo et al.** in view of **Soetokno et al.** as applied to **claims 1, 20, 29, 37** above, and further in view of **Duran (US 5,489,297)**.

DiMatteo et al. in view of **Soetokno et al.** disclose all of the claimed limitations except for the bioabsorbable material being polylactic acid. However, **Duran** teaches that it was known to make similar devices of polylactic acid (Column 11, Lines 53-61). It

would have been obvious to one having ordinary skill in the art at the time of the invention was made to comprise PLA, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. PLA is a good material for forming a bioabsorbable structure since it has a predictable degradation rate (Column 11, Lines 53-61).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK MASHACK whose telephone number is

Art Unit: 3773

(571)270-3861. The examiner can normally be reached on Monday-Thursday 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Mashack/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773